Introduction

Ethics review and approval are fundamental components of research activity. Identifying the most appropriate process to follow is not necessarily straightforward, and is determined by factors such as the characteristics of the research participants and where the research is taking place. The individual nature of most research projects means that there is no simple ‘one size fits all’ recommendation. This research guide offers general guidance, rather than definitive advice, and signposting to resources where more detailed information may be obtained on ethics approval issues.

Key areas covered:

1. Ethical principles.
2. Research governance in the United Kingdom
3. University ethics approval.
4. Health and social care research ethics approval
   4.1 Health Research Authority (HRA) and NHS Ethics Committee
   4.2 Research passports
   4.3 Social care research approval
   4.4 Local approvals and permissions
5. Research involving health or social care staff.
6. Research outside of statutory services.
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1. Ethical principles

The UK Policy Framework for Health and Social Care Research (2018) sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of people who access services and the public in health and social care research, by describing ethical conduct and proportionate management of health and social care research, to support and facilitate high-quality research in the UK.
The policy is applicable to organisations and individuals that have responsibilities for health and social care research; this includes funders, sponsors, researchers and their employers, research sites and care providers.

Failing to meet ethical, legal and professional obligations amounts to research misconduct (Universities UK 2012) and in some cases is unlawful (for example, when involving adults who lack capacity to consent).

For further information on research and ethical issues the Royal College recommends the UK Research Integrity Office’s Code of Practice for Research (UKRIO 2018). This reference tool supports researchers and research organisations to conduct research of the highest quality. The Code provides principles and standards for researchers and research organisations and includes a Recommended Checklist for Researchers, a one-page checklist for the key points of good practice in research, based on detailed standards provided by the Code.

2. Research Governance in the United Kingdom

The UK Policy Framework for Health and Social Care Research has replaced the separate research Governance Frameworks in each UK country with a single set of principles for the whole UK - The Integrated Research Application System (IRAS). IRAS is a single system for applying for the permissions and approvals for health and social care/community care research in the UK. IRAS is aligned with the new UK Policy Framework for Health and Social Care Research (2018). IRAS supports a single electronic submission regardless of which UK nation the lead R&D office is in. This change is part of the Four Nations NHS/HSC Compatibility Programme that aims to make the researcher experience of setting up a study the same across the UK and the four nations are developing compatible cross-border processes.

All applications to conduct UK research in or through NHS/HSC organisations must use the IRAS system. The process for submission is the same regardless of which UK nation the research is led from and whether or not NHS/HSC Research Ethics Committee (REC) review is required. However, as not all research conducted within the UK requires approval from an NHS REC; the Health Research Authority has produced a decision tool to help you to determine if your study requires this type of approval.

The decision regarding what ethics applications are necessary for a proposed research activity is something that researchers must determine in collaboration with their research supervisors and/or research team. In addition to an independent ethics review, researchers must also consider other permissions that may be required to enable them to undertake their research within specific organisations or locations. It is the responsibility of researchers, and sponsors of research, to decide what ethical review is needed to meet statutory requirements.
It is crucial that adequate time for obtaining ethics approval is included in the project timescale before the project may begin.

If your research involves undertaking the research on the premises of an NHS/HSC organisation, with NHS/HSC patients or with NHS/HSC staff, then you should always contact the local NHS/HSC R&D office as early as possible to discuss your research plans.

For more information about how to prepare and submit your IRAS application, and REC review, substantial step by step support is provided on the IRAS website and through their online guide.

3. **University ethics approval**

If the proposed research is being undertaken in part fulfilment of an academic award (for example, an MSc or PhD), the university the student is registered at will in most cases act as the research sponsor. This will also usually be the situation for research being undertaken by employees of a university. University research governance processes are usually hosted by a central research office within each university, but individual faculties, schools, or research institutes may have their own ethics approval committee.

Normally, where the proposal involves undertaking the research on the premises of an NHS/HSC organisation, with NHS/HSC patients or in some cases with NHS/HSC staff, the university will signpost directly to the IRAS system. Notification of IRAS approval is then provided to the University Committee. Researchers are therefore advised to establish well in advance the process they will need to follow. Information about a university’s procedures, necessary forms/online submission requirements, and committee dates should be available from a research supervisor or the university website.

4. **Health and social care research ethics approval**

4.1 **Health Research Authority (HRA) and NHS Research Ethics Committees**

The purpose of the Health Research Authority (HRA) is to protect and promote the interests of people who access services and the public in health research. HRA Approval brings together the assessment of governance and legal compliance, with an independent ethical opinion by a Research Ethics Committee so that you only need to submit one application. It applies across the UK where the NHS organisation has a duty of care to participants, either as people who access services or as NHS staff/volunteers. The HRA website provides the latest guidance on applying for ethical approval.

There are more than 80 NHS RECs across the UK. They exist to safeguard the rights, safety, dignity and well-being of research participants. RECs consist of up to 15 members, a third of
whom are ‘lay’ people. RECs review research proposals and give an opinion about whether the research is ethical. They also look at issues such as the participant involvement in the research.

A Central Booking System is in place which covers all bookings for a review by NHS RECs in the UK. After preparing your application, contact the Central Booking Service to book onto a REC meeting.

Ethics review should be proportionate to the scale and complexity of the research proposed. Therefore if research does not present any material ethical issues, it may be eligible for proportionate review by a sub-committee of a REC. Details on what constitutes ‘no material ethical issues’ and how proportionate approval can be requested are available on the HRA website.

Revised Governance Arrangements for Research Ethics Committees (GafREC) were implemented in September 2018 by the Health Research Authority and the UK health departments in Northern Ireland, Scotland and Wales and explain when review by these committees is required.

The updated policy document replaces the 2011 version, and the majority of changes have been made to take account of legal, policy and operational developments in the intervening time.

Only proposed research activity usually needs to be submitted for approval by an NHS REC. Service evaluation and audit projects are subject to different review processes, and in health services this is usually via NHS clinical governance departments. Researchers are advised to refer to the HRA website, which explains how to differentiate research from other activities, and to their Decision Tool.

4.2 Research passports
A research passport is required for non-NHS staff to obtain an Honorary Research Contract or Letter of Access (LOA) to enable them to carry out research in the NHS.

The research passport system provides:

- one set of checks on a researcher conducting research in the NHS;
- one standard form completed by the researcher and his/her employer, and validated by an NHS organisation;
- a completed Research Passport which is presented to all the relevant NHS organisations; and
- faster study start-up.

Application for a research passport is also made through the IRAS system and further information can be found in the HR Good Practice Resource Guide.
4.3 Social care research approvals
The HRA took formal responsibility for research in adult social care in January 2015. Some RECs are able to review social care research reviews, intergenerational studies involving adults and children or families and some proposals for social science studies situated in the NHS. Further details of the remit of social care RECs can be found here.

Applications to RECs able to review social care research are also booked through the Central Booking Service as above.

Social care research does not require review by a social care flagged REC if it is reviewed by another committee abiding by the Economic and Social Research Council’s (ESRC) Framework for Research Ethics (2015), unless the research involves NHS patients, people who access services or people who lack capacity as research participants. Other student research within the field of social care should ordinarily be reviewed by a university REC (UREC).

4.4 Local approvals or permissions for research
Individual organisations may also have a process by which approval and/or permission is given for research to take place. Any organisation within which a researcher wishes to carry out their research can apply their own qualifying conditions, and it remains their prerogative to withhold access (e.g. if they think the research is too disruptive or will not deliver benefits).

5. Research involving health or social care staff

The 2018 Governance Arrangements for Research Ethics Committees (GAfREC) states that NHS/SCREC research ethics committee approval is not required when research involves staff of the services in the four UK nations, who are recruited by virtue of their professional role (P12 section 2.3.14) except where it would otherwise require REC review under this document (for example, because there is a legal requirement for REC review, or because the research also involves patients or those who access services as research participants. Exceptions are outlined in GAfREC (2018)). This means that REC approval is not required for researchers who solely wish to recruit occupational therapists or health/social care professionals as participants.

However, it is important to note that research only involving the staff of health or social care services still does require permission from the relevant health/ care organisation.

Research projects involving staff should still undergo some form of independent ethical review. A university ethics approval process will in many cases be the way in which this requirement is met, or through an ethics review by an individual organisation/institution. It is essential that the researcher is familiar with the relevant research governance and ethics approval guidance documents to ensure that they are adhering to the necessary requirements.
6. Research outside of statutory services

Researchers should note that conducting research outside statutory health and social care organisations (for example, with or via a charity, in schools or independent practice) does not remove the need for an independent ethics review. Researchers must check with individual organisations what their requirements are before planning such research activity.

The ethics approval process may seem less clear where research is likely to involve those receiving a service from a charitable or voluntary sector organisation; via a social enterprise; third or independent sector service. GAfREC clarifies that REC review is required if a research project involves:

“potential research participants identified in the context of, or in connection with, their past or present use of the services listed above (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls” (2018, p10).

If the service is not being provided through a relevant country Health Department, it is still important to seek independent review for a research project. This may be via a university ethics committee (if applicable) or individual organisational arrangement.

Researchers working in non-statutory or independent sector organisations may have more difficulty finding an appropriate forum to undertake a review and should seek advice from their employer. Self-employed independent practitioners may need to obtain advice from the HRA, for example, if there are substantial ethical issues and no access to other review systems; make enquiries with the organisation from which they wish to recruit (e.g. charity, third sector body); or possibly buy in consultancy expertise for an independent review.

6.1 Market Research

Market research may be undertaken by professional market researchers, e.g. for public health research or on behalf of pharmaceutical or medical device companies. Where such research is conducted by professional market researchers in accordance with the principles set out in the Market Research Society Code of Conduct or with the Legal and Ethical Guidelines issued by the British Healthcare Business Intelligence Association (BHBIA), it does not require REC review, except where otherwise required by law, e.g. if it requires approval under the Mental Capacity Act (2005) (GAfREC 2018 p12 section 2.3.5). However other local organisational/institutional approvals may be required.
Tips for applying for ethics approval

- Plan plenty of time to factor in the ethics approvals process and any clarifications and/or revisions to the proposal that might be required.
- There is a wealth of information on websites, such as the HRA: explore and read all the guidance available before starting your application.
- Talk to a colleague who has been successful in making an application to an ethics committee.
- Ask your Trust or organisational R&D Department for advice.
- Keep records of any advice you receive about approvals and permissions required or not required. This could be valuable in providing evidence in circumstances when REC approval is not required, but when information is necessary to support local permission requests or any future submission for journal publication and/or an abstract for a scientific conference.

References


*All websites in this document were accessed on 26/6/19*

Need further information or advice?

Contact the RCOT Research and Development Administrator [kinza.ahmad@rcot.co.uk](mailto:kinza.ahmad@rcot.co.uk)